REMARKS

Claims 1-6 have been amended. New claims 7-12 are added. Claims 1-12 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicants respectfully request the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Rejection under 35 U.S.C. § 102(b) (De Haen)

Claims 1, 2, and 4 are rejected under 35 U.S.C. § 102(b) as being anticipated by De Haen, et al. (US 6,007,808).

The claims have been amended to "method" claims in place of the originally presented "composition" claims. The invention of the amended claims relates to "A method for promoting health in a subject comprising selectively proliferating *Lactobacillus casei* subsp. *casei* in the subject, comprising a step of administering a composition comprising a dextran to the subject" (claim 1). Support is found throughout the specification; see especially Example 3 on pages 17-18.

De Haen, et al. disclose a pharmaceutical or dietary composition for the prophylaxis and treatment of gastrointestinal disorders consisting of eubiotic bacteria and glutamine. De Haen, et al. disclose that the composition may include dextran, that *Lactobacillus casei* subsp. *casei* (specifically CNCM I-1391 and the like) produce a prophylactic and therapeutic effect on gastrointestinal infections and that glutamine influences the growth of *Lactobacillus casei* subsp. *casei.* However, in De Haen, et al. dextran is merely disclosed as a stabilizer of the lyophilized form (Example 6). Moreover, in the invention of De Haen, et al. dextran can be replaced with other stabilizers. Dextran is not an essential component. De Haen, et al. do not teach that dextran promotes proliferation of *Lactobacillus casei* subsp. *casei.*

The present invention differs from De Haen, et al. in that the presently claimed invention is directed to a method for selectively promoting proliferation of *Lactobacillus casei* subsp. *casei* by utilizing dextran. In the presently claimed invention, dextran is an essential component.

The present invention has been accomplished based on the finding that *Lactobacillus casei* subsp. *casei* specifically has dextran utilizing ability in a number of enteric bacteria. The

presently claimed invention is directed to a method for selectively proliferating *Lactobacillus casei* subsp. *casei* by utilizing this ability.

In contrast, De Haen, et al. do not teach that *Lactobacillus casei* subsp. *casei* has dextran utilizing ability and that the proliferation of *Lactobacillus casei* subsp. *casei* can be promoted by dextran.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 102(b) (Mitsuhashi)

Claims 1 and 3 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Mitsuhashi, et al. (EP 0382355).

Mitsuhashi, et al. disclose a growth promoting agent for bifid bacteria which contains dextran as an effective component. Mitsuhashi, et al. merely disclose that dextran has a promoting effect for proliferation of bifid bacteria, but do not teach a promoting effect for proliferation of *Lactobacillus casei* subsp. *casei.* Further, Mitsuhashi, et al. do not disclose a promoting effect for proliferation of *Lactobacillus casei* subsp. *casei* which is due to dextran utilizing ability.

The present invention is directed to a method for selectively promoting proliferation of *Lactobacillus casei* subsp. *casei* by utilizing the ability of this bacteria to proliferate on dextran. As shown in Tables 1- and 1-2 of the present specification on pages 15 and 16, of about 68 species tested, including other species of *Lactobacillus*, only *Lactobacillus casei* subsp. *casei* was able to proliferate on dextran. Accordingly, by providing dextran as a carbon source, growth of *Lactobacillus casei* subsp. *casei* is favored in a mixed culture including other bacteria which are unable to use this substrate.

Mitsuhashi, et al. disclose a growth-promoting agent for bifid bacteria, which contains dextran as an effective component. According to the teaching of Mitsuhashi, et al. at page 2, lines 38-52 of the specification, dextran does not have a bifid bacteria growth promoting effect in vitro. However, dextran does have bifid bacteria growth promoting effect in vivo.

Presumably, the growth promoting effect for bifid bacteria by dextran is not shown in vitro because bifid bacteria do not have dextran utilizing ability. However, a growth promoting

effect for bifid bacteria is shown in vivo since dextran is partially catabolized to oligosaccharides due to effect of other enteric bacteria or the like, and bifid bacteria can utilize the oligosaccharides and its growth is promoted.

Accordingly, Mitsuhashi, et al. do not teach a dextran utilizing ability of any bacteria and do not teach proliferation of *Lactobacillus casei* subsp. *casei* on dextran.

Although *Bifidbacterium* and *Lactobacillus* are both enteric microorganisms, they are different bacterial species and different genera. For example, *Bifidbacterium* is an obligate anaerobe bacillus and diverges V form or Y form and shows diversity. *Lactobacillus* is a facultative anaerobe bacillus.

The effect of the present invention is to provide a variety of excellent biological activities in vivo, originating from *Lactobacillus casei* subsp. *casei*, which is sustained in a living body, by selectively growing, proliferating and colonizing *Lactobacillus casei* subsp. *casei* in an intestine of a human being, animal or the like.

Such effect of the present invention is shown in the Examples (specifically Examples 3-7) and described in the specification and Drawings. For example, in Example 5, enhancement of cellular immunity by dextran and dextran plus *Lactobacillus casei* subsp. *casei* by oral administration of antigen was tested. Cellular immunity was significantly enhanced in BSA plus dextran and BSA plus *Lactobacillus casei* subsp. *casei* administered groups compared to the BSA administered group. Furthermore, cellular immunity in BSA plus dextran plus *Lactobacillus casei* subsp. *casei* administered group was even more greatly enhanced.

The excellent effects of the present invention cannot be provided by using any lactic acid bacteria. That is, the effect cannot be provided by using bacteria which do not have dextran utilizing ability. *Lactobacillus casei* subsp. *casei* has dextran utilizing ability and can utilize dextran and proliferate. On the contrary, bacteria which do not have dextran utilizing ability cannot utilize dextran as a nutritional source (carbon source) and must compete for nutrition with other enteric bacteria. *Lactobacillus casei* subsp. *casei* has dextran utilizing ability and can efficiently utilize dextran as a nutrition source.

As shown in Example 2 and Table 1 of the present specification, only specific bacteria, *Lactobacillus casei* subsp. *casei*, have dextran utilizing ability in tested enteric bacteria, and

species which belong to the genus *Bifidobacterium* and other tested species of the genus *Lactobacillus* do not have dextran utilizing ability.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 102(b) /103(a)

Claim 3 is rejected under 35 U.S.C. § 102 (b) as anticipated by or in the alternative, under 35 U.S.C. § 103(a) as obvious over De Haen et al. (US 6007808)

The claims have been amended to "method" claims in place of the originally presented "composition" claims. The invention of the amended claims relates to "A method for promoting health in a subject comprising selectively proliferating *Lactobacillus casei* subsp. *casei* in the subject, comprising a step of administering a composition comprising a dextran to the subject" (claim 1). Support is found throughout the specification; see especially Example 3 on pages 17-18.

De Haen, et al. disclose a pharmaceutical or dietary composition for the prophylaxis and treatment of gastrointestinal disorders consisting of eubiotic bacteria and glutamine. De Haen, et al. disclose that the composition may include dextran, that *Lactobacillus casei* subsp. *casei* (specifically CNCM I-1391 and the like) produce a prophylactic and therapeutic effect on gastrointestinal infections and that glutamine influences the growth of *Lactobacillus casei* subsp. *casei.* However, in De Haen, et al. dextran is merely disclosed as a stabilizer of the lyophilized form (Example 6). Moreover, in the invention of De Haen, et al. dextran can be replaced with other stabilizers. Dextran is not an essential component. Importantly, De Haen, et al. do not teach or suggest that dextran promotes proliferation of *Lactobacillus casei* subsp. *casei.*

The present invention differs from De Haen, et al. in that the presently claimed invention is directed to a method for selectively promoting proliferation of *Lactobacillus casei* subsp. *casei* by utilizing dextran. In the presently claimed invention, dextran is an essential component.

The present invention has been accomplished based on the finding that *Lactobacillus casei* subsp. *casei* specifically has dextran utilizing ability in a number of enteric bacteria. The presently claimed invention is directed to a method for selectively proliferating *Lactobacillus casei* subsp. *casei* by utilizing this ability.

In contrast, De Haen, et al. do not teach or suggest that *Lactobacillus casei* subsp. *casei* has dextran utilizing ability and do not teach or suggest the proliferation of *Lactobacillus casei* subsp. *casei* by dextran. Accordingly, Applicants respectfully submit that claim 1 is not taught or suggested by De Haen, et al. Claim 3 includes all of the limitations of claim 1. Accordingly, claim 3 also is patentable over De Haen, et al.

Regarding claim 3, De Haen, et al are completely silent regarding the size of the dextran used for stabilization. In contrast, Applicants have shown that the size of the dextran is important and that the molecular weight is preferably 2,000 to 40,000,000 (see Table 2 on page 17) for proliferation of *Lactobacillus casei* subsp. *casei*. De Haen, et al do not teach proliferation of *Lactobacillus casei* subsp. *casei* on dextran and do not teach the preferred molecular weight range.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 5 and 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over De Haen, et al (US 6007808) in view of Mitsuhashi, et al. (EP 382355).

Both references have been discussed above. As discussed above, neither De Haen, et al. nor Mitsuhashi, et al., taken separately or together, teach or suggest a method for treating and promoting health of a subject by selectively proliferating *Lactobacillus casei* subsp. *casei* by dextran as claimed.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or

other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: Nov. 29, 2007

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